

**STATIONARY SOURCE PERMIT TO OPERATE**

**National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Emissions  
Standard for Sterilization Facilities.**

This permit supercedes your permit dated September 26, 2006.

In compliance with the Federal Clean Air Act and the Commonwealth of Virginia  
Regulations for the Control and Abatement of Air Pollution,

Sterilization Services of Virginia  
5674 Eastport Boulevard  
Richmond, VA 23231

is authorized to operate

a commercial sterilization facility

located at

5674 Eastport Boulevard, in Henrico County

in accordance with the conditions of this permit.

Issued on XXX

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Director, Department of Environmental Quality

Permit consists of 11 pages.  
Permit Conditions 1 to 40.

## **INTRODUCTION**

This permit approval is based on the permit application dated January 24, 1990, including amendment sheets dated March 16, 1990; September 29, 1993; March 7, 1994; November 15, 1996; February 28, 1997; April 17, 1997; November 23, 1998, December 23, 1998, December 5, 2002, February 6, 2003, March 27, 2003, March 20, 2006, June 19, 2006 and September 7, 2006. Any changes in the permit application specifications or any existing facilities which alter the impact of the facility on air quality may require a permit. Failure to obtain such a permit prior to construction may result in enforcement action.

Words or terms used in this permit shall have meanings as provided in 9 VAC 5-10-10 of the State Air Pollution Control Board Regulations for the Control and Abatement of Air Pollution. The regulatory reference or authority for each condition is listed in parentheses () after each condition.

Annual requirements to fulfill legal obligations to maintain current stationary source emissions data will necessitate a prompt response by the permittee to requests by the DEQ or the Board for information to include, as appropriate: process and production data; changes in control equipment; and operating schedules. Such requests for information from the DEQ will either be in writing or by personal contact.

The availability of information submitted to the DEQ or the Board will be governed by applicable provisions of the Freedom of Information Act, §§ 2.2-3700 through 2.2-3714 of the Code of Virginia, § 10.1-1314 (addressing information provided to the Board) of the Code of Virginia, and 9 VAC 5-170-60 of the State Air Pollution Control Board Regulations. Information provided to federal officials is subject to appropriate federal law and regulations governing confidentiality of such information.

## **PROCESS REQUIREMENTS**

1. **Equipment List** - Equipment to be operated at this facility consists of:

<b>Equipment to be Constructed</b>				
<b>Reference No.</b>	<b>Equipment Description</b>	<b>Rated Capacity</b>	<b>Federal Requirements</b>	<b>Original Permit Date</b>
3S1	Ethylene Oxide Sterilizer	4938 ft <sup>3</sup>	40 CFR 63 Subpart O	September 26, 2006
E3	CET Packed Tower Scrubber			September 26, 2006
<b>Equipment permitted prior to the date of this permit</b>				
<b>Reference No.</b>	<b>Equipment Description</b>	<b>Rated Capacity</b>	<b>Federal Requirements</b>	<b>Original Permit Date</b>
1S1	Ethylene Oxide Sterilizer	4938 ft <sup>3</sup>	40 CFR 63 Subpart O	March 26, 1990
2S1	Ethylene Oxide Sterilizer	2469 ft <sup>3</sup>	40 CFR 63 Subpart O	March 26, 1990

1-7 AE	Seven (7) ethylene Oxide Aeration Rooms	1210.7 lbs/hr Ethylene oxide total		March 26, 1990
CEVs	Fugitive chamber exhaust vents			March 26, 1990
E1	Croll-Reynolds Packed Tower Scrubber			April 9, 2003
E2	Vacudyne Catlytic Oxidizer			April 9, 2003

(9 VAC 5-80-850)

2. **Requirements by Reference** – Except where this permit is more restrictive than the applicable requirement, this facility shall operate in conformance with 40 CFR 63, Subpart O, Ethylene Oxide Emissions Standard for Sterilization Facilities (MACT Standard).  
(9 VAC 5-50-260, 9 VAC 5-170-160, 9 VAC 5-60-90 and 9 VAC 5-60-100)

### **OPERATING/EMISSION LIMITATIONS**

3. **Throughput** - The facility shall use no more than 718,330 lbs per year of volatile organic compounds (ethylene oxide) calculated monthly for each consecutive 12 month period.  
(9 VAC 5-170-160, 9 VAC 5-80-1180 and 9 VAC 5-80-850)
4. **Emission Controls and Control Efficiency** - Ethylene oxide emissions from the Ethylene Oxide Sterilizer (Ref # 1S1 and 2S1) chamber vents shall be controlled by a packed tower scrubber (Ref # E1). The scrubber shall operate with a minimum control efficiency of 99%, to be demonstrated by parametric monitoring. The scrubber and sterilizers shall be provided with adequate access for inspection.  
(9 VAC 5-80-1180, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-850)
5. **Emission Controls and Control Efficiency** – Ethylene oxide emissions from the Ethylene Oxide Sterilizer (Ref # 3S1) chamber vent shall be controlled by a packed tower scrubber (Ref # E2). The scrubber shall operate with a minimum control efficiency of 99%, to be demonstrated by parametric monitoring. The scrubber and sterilizers shall be provided with adequate access for inspection.  
(9 VAC 5-80-1180, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-850)
6. **Emission Controls and Control Efficiency** – Ethylene oxide emissions from each aeration room vent shall be controlled by a catalytic oxidizer (Ref # E-3). The catalytic oxidizer shall operate with a control efficiency of 99%, or less than 1ppmv, whichever is less stringent, to be demonstrated by parametric monitoring. The catalytic oxidizer shall be provided with adequate access for inspection.  
(9 VAC 5-80-1180, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-850)
7. **Emission Controls and Control Efficiency** – The number of nitrogen washes and/or vacuum flushes of the sterilization chamber shall be in accordance with product requirements.  
(9 VAC 5-170-160 and 9 VAC 5-80-850)

8. **Emission Controls and Control Efficiency** – The three sterilization chambers and the seven aeration rooms shall be designed so that they shall not individually nor collectively operate without the control equipment being on line.  
(9 VAC 5-50-10 C, 9 VAC 5-50-410, 9 VAC 5-80-850 and 9 VAC 5-170-160)
9. **VOC Work Practice Standards** – At all times the disposal of volatile organic compounds shall be accomplished by taking measures, to the extent practicable, consistent with air pollution control practices for minimizing emissions. Volatile organic compounds shall not be intentionally spilled, discarded in sewers which are not connected to a treatment plant, or stored in open containers, or handled in any other manner that would result in evaporation beyond that consistent with air pollution practices for minimizing emissions.  
(9 VAC 5-50-20 F 9, VAC 5-80-1180 and 9 VAC 5-80-850)

### **MONITORING REQUIREMENTS**

10. **Monitoring Device Observation** – In Reference No.'s E1 and E3, the recirculation tank shall be equipped with a liquid level indicator to measure the scrubber liquor tank level. The liquid level indicator shall be maintained so that it is in proper working order at all times.  
(9 VAC 5-170-160, 9 VAC 5-50-20 C, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-850)
11. **Monitoring Device Observation** – In Reference No.'s E1 and E3, the scrubber liquor level in the recirculation tank shall be measured and recorded at least once per week. Monitoring is required during a week only if the scrubber unit has been operated. A low-flow alarm shall be installed to ensure adequate water flow to the scrubber. The low-flow alarm shall be maintained by the permittee such that it is in proper working order at all times. An annual internal inspection shall be conducted on the scrubber packing.  
(9 VAC 5-170-160, 9 VAC 5-50-20 C, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-850)
12. **Monitoring Device Observation** - In Reference No.'s E1 and E3, the volume of any liquids added to the scrubber system shall be recorded in a log book. This log book will be retained on-site for a minimum of the most recent five years.  
(9 VAC 5-170-160, 9 VAC 5-50-20 C9 and VAC 5-80-850)
13. **Monitoring Device Observation** – For Emission Unit E1, the operating limit for the packed tower scrubber shall not exceed the maximum liquor (recirculation) tank level of 8 feet 3 inches.  
(9 VAC 5-170-160, 9 VAC 5-50-20, 9 VAC 5-60-90 and 9 VAC 5-60-100 and VAC 5-80-850)
14. **Monitoring Device Observation** – For Emission Unit E3, the operating limit for the packed tower scrubber shall not exceed the maximum liquor (recirculation) tank level determined during the initial compliance test required by Condition 29.  
(9 VAC 5-170-160, 9 VAC 5-50-20, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-850)

15. **Monitoring Device Observation** – The permittee shall install, calibrate, operate, and maintain a temperature monitor accurate to 10F (5.6C) at the outlet to the catalyst bed. The accuracy of the temperature monitor shall be verified twice each calendar year with a reference temperature monitor traceable to National Institute of Standards and Technology standards or an independent temperature measurement device dedicated for this purpose. During accuracy checking, the probe of the reference device shall be at the same location as the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).  
(9 VAC 5-170-160, 9 VAC 5-50-20 C, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-850)
16. **Monitoring Device Observation**- A data acquisition system for the temperature monitor shall continuously monitor the oxidation temperature at the outlet to the catalyst bed. The outlet temperature shall be recorded on a continuous basis (from 15 minutes or shorter) and shall be retained on site for 5 years.  
(9 VAC 5-170-160, 9 VAC 5-50-20 C, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-850)
17. **Monitoring Devices** - The operating limit consists of the recommended minimum oxidation temperature of 280° F provided by the oxidation unit manufacturer for an operating limit.  
(9 VAC 5-170-160, 9 VAC 5-50-20 E, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-850)
18. **Monitoring Devices** - Beginning 5 years after the initial compliance test as per 40 CFR 63.363, the thermal oxidizer's catalyst bed will be replaced with new catalyst material minimally every five years.  
(9 VAC 5-80-850 and 9 VAC 5-170-160)
19. **Monitoring Devices** -The facility must demonstrate continuous compliance with each operating limit and work practice standard required under 40 CFR § 63.363 (compliance and performance provisions) (such as condition nos. 12, 15, and 16), except during periods of startup, shutdown, and malfunction, according to the methods specified in 40 CFR § 63.364 (monitoring requirements) (such as condition nos. 9, 10, 13, and 14).  
(9 VAC 5-50-400 and 9 VAC 5-50-410)

### **EMISSION LIMITATIONS**

20. **Emission Controls** - The exhaust stacks shall be constructed to minimum heights as specified below:

Scrubber exhaust stack	45 feet
Oxidizer exhaust stack	45 feet

(9 VAC 5-170-160, 9 VAC 5-50-10 C and 5-80-850)

21. **Process Emission Limits** – Emissions from the EO sterilizers shall not exceed the limitations specified below:

EO sterilizers 1S1 and 2S1 as exhausted through scrubber #1:

Volatile Organic Compounds 11.6 lb/hr  
(Ethylene Oxide)

EO sterilizer 3S1 as exhausted through scrubber #2:

Volatile Organic Compounds 7.7 lb/hr  
(Ethylene Oxide)

Combined operation of the three (3) EO sterilizers Unit Ref. 1S1, 2S1 and 3S1 as exhausted through scrubbers Unit Ref. E1 and E3:

Volatile Organic Compounds 3.44 tons/yr  
(Ethylene Oxide)  
(9 VAC 5-50-30, 9 VAC 5-80-1200, 9 VAC 5-50-410 and 9 VAC 5-80-850)

22. **Emission Controls** – Fugitive emissions from the oxidizer exhaust shall not exceed the limitations specified below:

Volatile Organic Compounds 0.36 lb/hr 0.11 tons/yr  
(Ethylene Oxide)  
(9 VAC 5-50-260 and 9 VAC 5-50-10 C and 9 VAC 5-80-850)

23. **Process Emission Limits** - Emissions from the chamber exhaust vents shall not exceed the limitations specified below:

Volatile Organic Compounds 14.53 lb/hr 4.31 tons/yr  
(Ethylene Oxide)  
  
(9 VAC 5-50-260 and 9 VAC 5-80-850)

24. **Visible Emissions** - Visible emissions from each of the exhaust stacks shall not exceed zero percent opacity.  
(9 VAC 5-170-160, 9 VAC 5-50-20, 9 VAC 5-50-10 C and 9 VAC 5-80-850)

**GENERAL CONDITIONS**

25. **Right of Entry** - The permittee shall allow authorized local, state, and federal representatives, upon the presentation of credentials:

- a. To enter upon the permittee's premises on which the facility is located or in which any records are required to be kept under the terms and conditions of this permit;
- b. To have access to and copy at reasonable times any records required to be kept under the terms and conditions of this permit or the State Air Pollution Control Board Regulations;
- c. To inspect at reasonable times any facility, equipment, or process subject to the terms and conditions of this permit or the State Air Pollution Control Board Regulations; and
- d. To sample or test at reasonable times.

For purposes of this condition, the time for inspection shall be deemed reasonable during regular business hours or whenever the facility is in operation. Nothing contained herein shall make an inspection time unreasonable during an emergency.

(9 VAC 5-50-30, 9 VAC 5-80-1200, 9 VAC 5-50-410 and 9 VAC 5-80-850)

26. **Emissions Testing** - The permitted facility shall be constructed so as to allow for emissions testing at any time using appropriate methods. Test ports will be provided at the following locations:

Scrubber exhaust stack  
Oxidizer exhaust stack

(9 VAC 5-50-30 F and 9 VAC 5-80-850)

27. **Emissions Testing** - The commercial sterilization facility shall be modified so as to allow for emissions testing upon reasonable notice at any time, using appropriate methods. This includes constructing the facility/equipment such that volumetric flow rates and pollutant emission rates can be accurately determined by applicable test methods and providing a stack or duct that is free from cyclonic flow. Sampling ports shall be provided when requested and safe sampling platforms and access shall be provided.

9 VAC 5-50-30 F, 9 VAC 5-80-1180 and 9 VAC 5-80-850)

28. **Maintenance/Operating Procedures** – At all times, including periods of start-up, shutdown and malfunction, the permittee shall, to the extent practicable, maintain and operate the affected source, including associated air pollution control equipment, in a manner consistent with good air pollution control practices for minimizing emissions.

(9 VAC 5-50-20 E and 9 VAC 5-80-850)

### **INITIAL COMPLIANCE DETERMINATION**

29. **Stack Test** - Initial performance tests shall be conducted for ethylene oxide from the Packed Tower Scrubber (Unit ID E3) and Ethylene Oxide Sterilizer (Unit ID 3S1) exhaust stacks to determine compliance with the emission limits and control efficiency requirements contained in Condition(s) 14, 21, 23 and 24. The tests shall be performed, and reported within 60 days after achieving the maximum production rate at which the facility will be operated but in no event later than 180 days after start-up of the permitted facility. Tests shall be conducted and reported and data reduced as set forth in 9 VAC 5-50-30 and 9 VAC 5-60-30, EPA test Methods 18 & 205 and procedures contained in each applicable section or subpart listed in 40 CFR 63.365, 9 VAC 5-50-410 and 9 VAC 5-60-70. The details of the tests are to be arranged with the Piedmont Regional Office. The permittee shall submit a test protocol at least 30 days prior to testing. Two copies of the test results shall be submitted to the Piedmont Regional Office within 60 days after test completion.

(9 VAC 5-50-30, 9 VAC 5-80-1200)

### **RECORDKEEPING AND REPORTING REQUIREMENTS**

30. **Permit Suspension/Revocation** - The permittee shall maintain records of all emission data and operating parameters necessary to demonstrate compliance with this permit. The content of and format of such records shall be arranged with the Director, Piedmont Region. These records shall include, but are not limited to:

- a. Annual usage of volatile organic compounds (ethylene oxide), calculated monthly as the sum of each consecutive 12 month period.
- b. The volume of liquid removed from each scrubber system, calculated monthly as the sum of each consecutive 12 month period.
- c. The volume of liquid added to each scrubber system, calculated monthly as the sum of each consecutive 12 month period.
- d. The weekly liquid level in each scrubber supply tank.
- e. The liquid level of each scrubber feed tank prior to the removal and after the addition of any liquid to the system.
- f. Temperature monitoring data for the catalytic oxidizer.
- g. Calibration data for each temperature monitor.
- h. Records to demonstrate compliance with the work practice outlined in condition no. 18 for the catalytic oxidizer shall consist of the compliance test, data analysis, and if catalyst is replaced, proof of replacement.
- i. Records for all sources which are subject to 40 CFR § 63.362 shall comply with the recordkeeping requirements in 40 CFR § 63.10(b) and (c), according to the applicability in Table 1 of 40 CFR § 63.360, and in section 40 CFR § 63.367 (recordkeeping requirements).

These records shall be available for inspection by the DEQ and shall be current for the most recent five years.

(9 VAC 5-50-50, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-850)

31. **MACT Reporting** - For all sources which are subject to the emission standards in 40 CFR § 63.362 (Standards), the owner/operator/permittee shall fulfill all reporting requirements in 40 CFR §§ 63.10(a), (d), (e), and (f) of subpart A of 40 CFR Part 63, according to the applicability in Table 1 of 40 CFR § 63.360. These reports will be made to the Administrator at the appropriate address identified in 40 CFR § 63.13 of subpart A of 40 CFR Part 63.  
(9 VAC 5-170-160, 9 VAC 5-60-90, 9 VAC 5-60-100 and 9 VAC 5-80-940)

32. **MACT Reporting** - Content and submittal dates for deviations and monitoring system performance reports - all deviations and monitoring system performance reports and all summary reports, if required per 40 CFR § 63.10(e)(3)(vii) and (viii), shall be delivered or postmarked within 30 days following the end of each calendar half or quarter as appropriate

(40 CFR § 63.10(e)(3)(i) through (iv) for applicability). Written reports of deviations from an operating limit shall include all information required in 40 CFR § 63.10(c)(5) through (13), as applicable in Table 1 of 40 CFR § 63.360, and information from any calibration test in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

(9 VAC 5-170-160, 9 VAC 5-60-90, and 9 VAC 5-60-100 (40 CFR 63.366(a)(3)) and 9 VAC 5-80-850)

33. **Permit Invalidation** – This permit to modify the Ethylene Oxide Sterilizer (Unit ID 3S1) and construct the CET Packed Tower Scrubber (Unit ID E3) shall become invalid, unless an extension is granted by the DEQ, if:

- a. A program of continuous modification, reconstruction, or modification is not commenced within the latest of the following:
  - i. 18 months from the date of this permit;
  - ii. Nine months from the date that the last permit or other authorization was issued from any other governmental entity;
  - iii. Nine months from the date of the last resolution of any litigation concerning any such permits or authorization; or
- b. A program of modification, reconstruction, or modification is discontinued for a period of 18 months or more, or is not completed within a reasonable time, except for a DEQ approved period between phases of a phased construction project.

(9 VAC 5-80-1210 and 9 VAC 5-80-850)

34. **Permit Suspension/Revocation** - This permit may be suspended or revoked if the permittee:

- a. Knowingly makes material misstatements in the permit application or any amendments to it;
- b. Fails to comply with the conditions of this permit;
- c. Fails to comply with any emission standards applicable to a permitted emissions unit, included in this permit;
- d. Causes emissions from the stationary source which result in violations of, or interfere with the attainment and maintenance of, any ambient air quality standard; or
- e. Fails to operate in conformance with any applicable control strategy, including any emission standards or emission limitations, in the State Implementation Plan in effect at the time an application for this permit is submitted.

(9 VAC 5-80-1210 F and 9 VAC 5-80-850)

35. **Right of Entry** - The permittee shall allow authorized local, state, and federal representatives, upon the presentation of credentials:

- a. To enter upon the permittee's premises on which the facility is located or in which any records are required to be kept under the terms and conditions of this permit;
- b. To have access to and copy at reasonable times any records required to be kept under the terms and conditions of this permit or the State Air Pollution Control Board Regulations;
- c. To inspect at reasonable times any facility, equipment, or process subject to the terms and conditions of this permit or the State Air Pollution Control Board Regulations; and
- d. To sample or test at reasonable times.
- e. For purposes of this condition, the time for inspection shall be deemed reasonable during regular business hours or whenever the facility is in operation. Nothing contained herein shall make an inspection time unreasonable during an emergency.

(9 VAC 5-170-130, 9 VAC 5-80-1180 and 9 VAC 5-80-850)

36. **Maintenance/Operating Procedures** – At all times, including periods of start-up, shutdown, and malfunction, the permittee shall, to the extent practicable, maintain and operate the affected source, including associated air pollution control equipment, in a manner consistent with good air pollution control practices for minimizing emissions.

- a. The permittee shall take the following measures in order to minimize the duration and frequency of excess emissions, with respect to air pollution control equipment:
- b. Develop a maintenance schedule and maintain records of all scheduled and non-scheduled maintenance.
- c. Maintain an inventory of spare parts.
- d. Have available written operating procedures for equipment. These procedures shall be based on the manufacturer's recommendations, at a minimum.
- e. Train operators in the proper operation of all such equipment and familiarize the operators with the written operating procedures, prior to their first operation of such equipment. The permittee shall maintain records of the training provided including the names of trainees, the date of training and the nature of the training.
- f. Records of maintenance and training shall be maintained on site for a period of five years and shall be made available to DEQ personnel upon request.

(9 VAC 5-50-20 E, 9 VAC 5-80-1180 D and 9 VAC 5-80-850)

37. **Record of Malfunctions** – The permittee shall maintain records of the occurrence and duration of any bypass, malfunction, shutdown or failure of the facility or its associated air pollution control equipment that results in excess emissions for more than one hour. Records shall include the date, time, duration, description (emission unit, pollutant affected, cause), corrective action, preventive measures taken and name of person generating the record.  
(9 VAC 5-20-180 J, 9 VAC 5-80-1180 D and 9 VAC 5-80-850)
38. **Notification for Facility or Control Equipment Malfunction** - The permittee shall furnish notification to the Director, Piedmont Region of malfunctions of the affected facility or related air pollution control equipment that may cause excess emissions for more than one hour, by facsimile transmission, telephone or telegraph. Such notification shall be made as soon as practicable but no later than four daytime business hours after the malfunction is discovered. The permittee shall provide a written statement giving all pertinent facts, including the estimated duration of the breakdown, within two weeks of discovery of the malfunction. When the condition causing the failure or malfunction has been corrected and the equipment is again in operation, the permittee shall notify the Piedmont Region.  
(9 VAC 5-20-180 C, 9 VAC 5-80-1180 and 9 VAC 5-80-850)
39. **Violation of Ambient Air Quality Standard** - The permittee shall, upon request of the DEQ, reduce the level of operation or shut down a facility, as necessary to avoid violating any primary ambient air quality standard and shall not return to normal operation until such time as the ambient air quality standard will not be violated.  
(9 VAC 5-20-180 I, 9 VAC 5-80-1180 and 9 VAC 5-80-850)
40. **Change of Ownership** - In the case of a transfer of ownership of a stationary source, the new owner shall abide by any current permit issued to the previous owner. The new owner shall notify the Director, Piedmont Region of the change of ownership within 30 days of the transfer.  
(9 VAC 5-80-1240 and 9 VAC 5-80-850)
41. **Permit Copy** - The permittee shall keep a copy of this permit on the premises of the facility to which it applies.  
(9 VAC 5-80-1180 and 9 VAC 5-80-850)